UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

ISD

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/121,211	07/23/98	SHINOHARA T	B0801/7116

HM12/0929

EDWARD R. GATES
WOLF, GREENFIELD & SACKS
600 ATLANTIC AVENUE
BOSTON MA 02210

EXAMINER	
ROMEO, D	
ART UNIT	**PAPER NUMBER**
1646	8

DATE MAILED: 09/29/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

1- File Copy

PTO-90C (Rev. 2/95)

Office Action Summary	Application No. 09/121,211	Applicant(s) Shinohara et al.
	Examiner David S. Romeo	Group Art Unit 1646

☒ Responsive to communication(s) filed on *12-17-98*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *See the attached, para. 1* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *See the attached para 2.* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Disposition of Claims

1. Claims 1-22, 26, 29, 31, 34, 35, 44, 45, 47, 49, 52, 55, 56, 58, 61, 64, and 70 is/are pending in the application.

2. Claims 1-22, 26, 29, 31, 34, 35, 44, 45, 47, 49, 52, 55, 56, 58, 61, 64, and 70 are subject to restriction or election requirement.

Election/Restriction

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, and 26, to the extent that they are drawn to polynucleotides encoding a polypeptide comprising the amino acid sequence of SEQ ID NO:2, complementary nucleic acid molecules thereof, and a recombinant method of making the encoded polypeptide, classified in class 435, subclass 69.1.

II. Claims 12-16, 22, 29, and 47, to the extent that they are drawn to a polypeptide comprising the amino acid sequence of SEQ ID NO:2 and pharmaceutical compositions comprising same, classified in class 530, subclass 350.

III. Claims 17, 18, 20, 21, and 26, to the extent that they are drawn to an antibody that binds a polypeptide comprising the amino acid sequence of SEQ ID NO:2, classified in class 530, subclass 387.9.

IV. Claim 19, to the extent that it is drawn to an antibody that binds a polypeptide comprising an amino acid sequence selected from the group consisting of SEQ ID NO:4, 6, and 8, classified in class 530, subclass 387.9.

V. Claim 31, drawn to a method of suppressing anti-LEDGF antibodies by administering a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, classified in class 514, subclass 12.

VI. Claim 35, drawn to a diagnostic assay for LEDGF to the extent that LEDGF is a polypeptide comprising the amino acid sequence of SEQ ID NO:2, classified in class 435, subclass 7.1.

VII. Claims 44, 49, 52, and 55 to the extent that they are drawn to a method of gene therapy using anti-sense nucleic acid molecules, classified in class 514, subclass 44.

VIII. Claim(s) 58, 61, 64, and 70 to the extent that they are drawn to a method of treatment comprising administering a polypeptide comprising the amino acid sequence of SEQ ID NO:2, classified in class 514, subclass 12.

IX. Claim(s) 47, 61, 64, and 70, to the extent that they are drawn to a pharmaceutical composition comprising a nucleic acid molecule and a method of gene therapy

using a nucleic acid molecule that encodes a polypeptide comprising the amino acid sequence of SEQ ID NO:2, classified in class 514, subclass 44.

X. Claim(s) 44, 49, 52, 55 to the extent that they are drawn to a method of administering an antibody that binds a polypeptide comprising the amino acid sequence of SEQ ID NO:2, classified in class 424, subclass 139.1.

4. The inventions are distinct, each from the other because of the following reasons:

a. The polynucleotides of Invention I are related to the polypeptides of Invention II by virtue of encoding same. The polynucleotide has utility for the recombinant production of the polypeptide in a host cell. Although the polynucleotide and polypeptide are related since the polynucleotide encodes the specifically claimed polypeptide, they are distinct inventions because they are physically and functionally distinct chemical entities, and the polypeptide product can be made by another and materially different process, such as by synthetic polypeptide synthesis or purification form the natural source. Further, the polynucleotide may be used for processes other than the production of the polypeptide, such as a nucleic acid hybridization assay.

b. The polynucleotide of invention I and the antibody of Invention II are related by virtue of the polypeptide that is encoded by the polynucleotide and necessary for the production of the antibody. However, the polynucleotide itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these inventions are distinct.

c. Inventions I and each of VII and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide could be used for the recombinant production of the encoded polypeptide or as a probe in a hybridization assay.

d. The polypeptide of invention II is related to the antibody of Invention III by virtue of being the cognate antigen, necessary for the production of the antibody. Although the polypeptide and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the polypeptide can be used in another materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or in assays for the identification of agonists or antagonists.

e. Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide could be used in the method of invention VIII.

f. Inventions II and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide could be used in the method of invention V.

g. Inventions III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody could be used in the method of invention X.

h. Inventions III and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody could be used in the method of invention VI.

i. The following pairwise combinations of products are independent and distinct, wherein neither member of a pair is required for the production or use of the other, and wherein each of the pair can be manufactured independently of the other and used for independent and distinct purposes: I and IV; II and IV; III and IV.

j. The following pairwise combinations of products and methods are independent and distinct, wherein the respective products may neither be produced by, nor used in the respective methods: I and each of V, VI, VIII, X; II and each of VI, VII, IX, X; III and each of V, VII, VIII, IX; IV and each of V-X.

k. The following pairwise combinations of methods are independent and distinct, wherein each member of a pair performs different functions, using different starting materials and/or process steps and/or with different outcomes: V and each of VI-X; VI and each of VII-X; VII and each of VIII-X; VIII and each of IX-X; IX and X.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. Because these inventions are distinct for the reasons given above and the searches required are not coextensive, restriction for examination purposes as indicated is proper.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. If group IV is elected, claim 19 is generic to a plurality of disclosed patentably distinct species comprising an antibody that binds to a polypeptide comprising the amino acid sequence of SEQ ID NO:4, an antibody that binds to a polypeptide comprising the amino acid sequence of

SEQ ID NO:6, and an antibody that binds to a polypeptide comprising the amino acid sequence of SEQ ID NO:8. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Each of these compounds is materially distinct.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Formal Matters

11. Applicants are requested to provide a computer file on floppy disk of the GenBank Accession numbers only in Table III in American Standard Code for Information Interchange (ASCII) text. This is required in order that a meaningful search and examination of Claim 4 can be conducted. It is suggested that the disk be hand delivered or sent via Federal Express to the examiner at the following address:

Commissioner of Patent and Trademarks
Attn.: Examiner David S. Romeo, Art Unit 1646
U.S. Patent and Trademark Office
Crystal Mall 1, 7th floor
1911 S. Clark Str.
Arlington, VA 22202

DO NOT SEND MATERIALS VIA U.S. EXPRESS MAIL. U.S. Express Mail will not deliver to this address.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David S. Romeo whose telephone number is (703) 305-4050. The examiner can normally be reached on Monday through Friday from 6:45 a.m. to 3:15 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310.

Official papers filed by fax should be directed to (703) 308-4242.

Faxed draft or informal communications should be directed to the examiner at (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID ROMEO
PATENT EXAMINER
September 27, 1999